

PATENT

DOCKET NO. 10013.0005US

REMARKS

Applicants are in receipt of the Office Action mailed December 10, 2007, and have the following remarks. Applicants note and appreciate that the Examiner has not repeated, and therefore withdrawn, the rejection of claims 1-9 and 14-22 pursuant to 35 U.S.C. §102(b) over Parce et al.

Objections to the Claims

Claims 8, 9, 12 and 13 were objected to as being in improper multiple dependent claims form due to their dependence from cancelled claim 7. Claims 8, 9 and 12 have been amended to indicate that they depend from claim 1. Claim 13, which depends from claim 12 has not been amended. Applicants therefore respectfully submit that this objection is now moot.

Rejection of Claims 10-13 pursuant to 35 USC §103(a)

Claims 1-4, 8, 9, and 12-22 were rejected as allegedly obvious over U.S. Patent No. 5,942,443, to Parce et al., in view of U.S. Patent No. 5,837,115 to Austin et al. After carefully considering the Examiner's arguments, Applicants respectfully traverse this rejection for the following reasons.

Obviousness is determined using the analytical framework set forth by the United States Supreme Court in *Graham v. John Deere Co.*, 381 U.S. 1(1966)(hereinafter "*Graham*"). Under this analytical framework, an invention cannot be considered obvious (and thus in violation of 35 U.S.C. §103(a)) unless the difference between the teachings of the prior art and of the claimed invention when taken as a whole are such that a person of ordinary skill in the art would find the claimed invention obvious in light of the prior art.

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The United States Supreme Court's recent decision in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_ U.S.P.Q.2d \_\_\_ (2007) affirms in every regard the standards set forth in *Graham*. Moreover, the *KSR* court indicated that in a proper rejection on obviousness grounds the Examiner must articulate reasoning with some rational underpinning to support the legal conclusion of obviousness, *id.*, slip op. at 14, such as "a reason that would have prompted a person of ordinary skill in the relevant field to combine the [known] elements in the way the claimed new invention does." *Id.*, slip op. at 15.

The presently claimed invention is drawn to devices for studying cell motility, migration, and deformation. The devices are made so that cells may be introduced in a test sample into a fluid medium into a channel of the device containing at least two channels connected by at least one through passage, and studying the migration and deformation of the cells through the through passage.

U.S. Patent No. 5,942,443, to Parce et al. is drawn to a device and method for performing high throughput screening assays of drugs. The devices and method concern continuous flow assays wherein test compounds are injected into a channel, are mixed with bioactive reagents in a fluid stream, and a biological response is automatically detected at a location in a channel downstream from the mixing point.

U.S. Patent No. 5,837,115 to Austin et al., concerns electrophoresis methods capable of being configured to fractionate or separate various substances, including DNA, proteins, polymers, and cells. Importantly, the devices described in Austin will vary according to the material being separated, but, once such a material is chosen the "object of the [Austin] invention is to provide a lattice structure in which the distribution, size and shape of the pore[s] therein are substantially uniform." Austin col. 4, line 49-52. While Austin describes various shapes of barriers within channeled devices, and explains that obstacles can have a staggered pattern, or "any predetermined and reproducible pattern", wherein each of the obstacles is separated from an adjacent obstacle by a predetermined separation distance ( $S_r$ ) to form passages, Austin nowhere describes or suggests a single device in which "the widths of the passages increases along the length of the partitioning wall", as is now claimed in every pending claim in the present application and illustrated in Fig. 9 of the present specification.

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Neither does Parce describe such a feature. In addition, the Examiner has not provided any evidence showing why a person of ordinary skill in the art, in possession of both Parce and Austin, would be led to make the present device with a reasonable expectation of success.

In response to Applicants' comments on the obviousness rejection over Parce and Austin contained in the previous Reply, the Examiner states in the Response to Arguments as follows:

To Applicant's argument that the presently claimed device is motivated from a desire to study cell motility, migration and deformation, while Parce and Austin are designed for performing high throughput screening or for fractionating microstructures, the Examiner states that an intended use does not distinguish a prior art structure "satisfying the claimed structural limitations" from the presently claimed device. In support thereof, the Examiner cites *Ex Parte Masham*, 2 U.S.P.Q. 2d 1647 (Bd. Pat. Appeals & Inter. 1987).

Respectfully, the Examiner has not alleged that all the "structural limitations" of claims 1-4, 8, 9, and 12-22 are satisfied by either Parce or Austin alone. If the Examiner did so allege, the rejection would be pursuant to 35 U.S.C. §102 rather than 35 U.S.C. §103. *Masham* is a decision of the Board upon appeal of a 35 U.S.C 102(b) anticipation rejection, not an obviousness rejection. Moreover, the rule articulated by the Examiner requires "a [single] prior art structure" satisfying all the claimed structural limitations of a claim at issue. The Examiner has not provided any example of such a single prior art structure.

Moreover, with regard to obviousness under 35 U.S.C. §103(a), the central question under *Graham v. John Deere* is whether the difference between the teachings of the prior art and the claimed invention when taken as a whole are such that a person of ordinary skill in the art would find the claimed invention obvious in light of the prior art. In such an inquiry, the intended use of a prior art invention is clearly probative evidence of how such a person would view the present invention based upon the prior art (Parce and Austin).

Secondly, the Applicants pointed out in their reply of November 5, 2007 that neither Parce et al. and/or Austin et al. teach that the width of the passages increases along the length of

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the partitioning wall. The Examiner has responded by admitting that Austin et al. "does not teach directly that 'the width of the passages increases along the length of the partitioning wall', but states that Austin et al. "indirectly teaches the same, based on the statement that 'each of the obstacles 39 is separated from an adjacent obstacle 39 by a predetermined distance  $S_d$ '" (citing Austin et al., column 10, lines 52-53).

However, upon study of the passages referenced by the Examiner, Applicants can see no support whatsoever for the Examiner's statement that Austin et al. either directly or indirectly teaches that the width of the passages increases along the length of the partitioning wall. Column 10, lines 52 and 53 of Austin et al. does indeed state that each of the obstacles are separated from adjacent obstacles by the distance  $S_d$ . This is shown graphically in Fig. 4. As can be seen, if the distance between each obstacle 39 and each adjacent obstacle 39 by  $S_d$ , then the width of the "passages" between obstacles will also be  $S_d$ , and Austin does not indicate that  $S_d$  will change in a single device or array.

It is true that Austin does disclose that the separation distance  $S_d$  may vary depending upon whether the migration of microstructures through the pores are DNA molecules, viruses and bacterial cells, or mammalian cells. However, there is absolutely no disclosure or suggestion that this variation might occur in a single device or array. And, even assuming *arguendo* such disclosure did exist, there is absolutely no inference or disclosure, either direct or indirect, that an increase of passage width would occur in a single device as a function of the length of the partitioning wall, as is currently claimed. In other words, the variation of widths in the currently claimed devices are neither random, nor do they decrease as a function of length – instead, and very specifically, the passage widths increase. The Examiner has not pointed out why this would be obvious in light of the prior art.

There is therefore no basis of record upon which the Examiner may reasonably conclude that a person of ordinary skill in the art, being acquainted with the disclosures of Parce and Austin, would conclude that the invention claimed in the present application is predictable or otherwise obvious.

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CONCLUSION

For the reasons stated above, the claims are now believed to be in condition for allowance, and Applicants respectfully request a Notice to that effect.

No fee is thought due in connection with the present communication. However, if any fee is now due, please use Deposit Account 50-4004 for the payment of such deficiency, or to credit any overpayment.

Respectfully submitted,

Date:

2/15/08



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